

#12/B  
9/10  
11/6/02

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE FAX RECEIVED

Applicants: Nikolich-Zugich, et al. Conf. No.: 2225 NOV 05 2002  
Serial No.: 09/719,494 Examiner: DiBrino GROUP 1600  
Filing Date: December 13, 2000 Art Unit: 1644  
For : Vaccination Strategy to Prevent and Treat Cancers

RESPONSE TO RESTRICTION REQUIREMENT

Asst. Commissioner for Patents  
Washington, D.C. 20231

Responsive to the Restriction Requirement mailed October 2, 2002 for the above-captioned application, please amend the application as follows:

In the claims:

- BI 4. (Amended) The method of claim 3, wherein the target peptide and the immunogenic portion of the therapeutic antigen each consist of from 8 to 10 amino acids.

REMARKS

Claim 4 has been amended to correct a typographical error in the dependency of the claim.

Responsive to the Restriction Requirement mailed October 2, 2002 for the above-captioned application, Applicants hereby elect the claims of Group I, Claims 1-4, 9 and 11-16, with traverse. Applicants further elect gp75 and the sequence of Seq. ID. No. 12, but traverse the requirement for an election of species. Applicants further submit that claims 7 and 8 should be included in this group, since they encompass both peptide and nucleic acid antigens. Claims 1-4, 7-9, and 11-14 read on the elected species.

The undersigned certifies that this paper is being submitted by facsimile transmittal to the United States Patent and Trademark Office at 703-308-4315 on November 4, 2002

Marina T. Larson  
Marina T. Larson, PTO 32,038

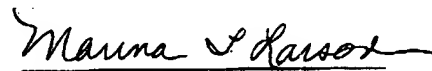
As a first matter, it is noted that the Examiner's justification for asserted lack of unity is the Bakker reference which the Examiner asserts teaches "an immunogenic class I MHC-binding peptide derived from a weakly immunogenic target peptide." The Examiner has provided neither evidence nor reasoning, however, to support this characterization of the reference and of gp100 as a weakly immunogenic peptide. gp100 is an inherently immunogenic peptide, and is not a weakly immunogenic peptide within the meaning of this application.

Weakly immunogenic does not mean merely that the epitope can be improved, which is all that Bakker is doing. It means, as stated in the present specification, that the unmodified antigen "is unable to induce activation and differentiation of effector CTL's." (Page 3, lines 19-20). This is an important group of antigens, because as a result of their weak immunogenicity, they do not induce tolerance in the immune system. Thus, because there is no tolerance to break, they are suitable targets for anti-tumor vaccination.

For this reason, Applicants submit that the restriction based on lack of unity is in error, because the teachings of the cited art do not render any of the claims unpatentable. Furthermore, the basis for this requirement is a section of the statute which is not applicable to PCT National Phase applications which are governed by the Unity of Invention Standard and not the restriction requirement. Reconsideration of the restriction requirement is respectfully requested.

For the foregoing reasons, Applicants submit that the restriction requirement in this instance should be withdrawn, and that all of the claims should be examined.

Respectfully submitted,



Marina T. Larson, Ph.D.  
Patent Office Reg. No. 32,038  
Attorney for Applicants  
(970) 468-6600

MARKED UP COPY OF AMENDED CLAIM

4. (Amended) The method of claim [2] 3, wherein the target peptide and the immunogenic portion of the therapeutic antigen each consist of from 8 to 10 amino acids.